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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/847,208	05/01/01	SAXON	A UC067.002A

020995 HM22/0628
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EXAMINER

HUYNH, P

ART UNIT	PAPER NUMBER
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1644

3

DATE MAILED:

06/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/847,208

Applicant(s)

SAXON ET AL.

Examiner

"Neon" Phuong Huynh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE One MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.
2. **Please Note:** In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot program. If you have any questions or suggestions please contact Paula Hutzell, Ph.D., Supervisory Patent Examiner at Paula.Hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.
3. Claims 1-72 are pending.

Election/Restrictions

- I. Claims 1-3, 5, 7-8, 10-11, 13-15, 17, 19-41 and 62-67, drawn to an isolated fusion molecule comprising a first polypeptide sequence of IgG immunoglobulin heavy chain constant region, functionally connected to a second polypeptide sequence capable of binding to high affinity Fc ϵ RI via a polypeptide linker and a third sequence from food allergen, a pharmaceutical composition comprising said fusion molecule and an article comprising said fusion molecule, classified in Class 424, subclass 192.1.
- II. Claims 1-3, 5, 7-8, 10-11, 13, 16-17, 19-41 and 62-67, drawn to an isolated fusion molecule comprising a first polypeptide sequence of IgG immunoglobulin heavy chain constant region, functionally connected to a second polypeptide sequence capable of binding to high affinity Fc ϵ RI via a polypeptide linker and a third sequence from pollen allergen, a pharmaceutical composition comprising said fusion molecule and an article comprising said fusion molecule, classified in Class 424, subclass 192.1.
- III. Claims 1-2, 4, 6-7, 9-10, 12, 13-15, 18-19, 22-39 and 62-67, drawn to an isolated fusion molecule comprising a first polypeptide sequence of IgG immunoglobulin heavy chain

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- constant region, functionally connected to a second polypeptide sequence capable of binding to low affinity FcεRII (CD23) via a polypeptide linker and a third sequence from food allergen, a pharmaceutical composition comprising said fusion molecule and an article comprising said fusion molecule, classified in Class 424, subclass 192.1.
- IV. Claims 1-2, 4, 6-7, 9-10, 12, 13, 16, 18-19, 22-39 and 62-67, drawn to an isolated fusion molecule comprising a first polypeptide sequence of IgG immunoglobulin heavy chain constant region, functionally connected to a second polypeptide sequence capable of binding to low affinity FcεRII (CD23) via a polypeptide linker and a third sequence from pollen allergen, a pharmaceutical composition comprising said fusion molecule and an article comprising said fusion molecule, classified in Class 424, subclass 192.1.
- V. Claims 42-54, drawn to a single-chain fusion molecule comprising a first polypeptide sequence having at least 90% sequence identity with the amino acid sequence of SEQ ID NO: 3 and capable of specific binding to a native human FcγRIIb receptor, functionally connected to a second polypeptide sequence at least 90% identity with amino acid sequence of SEQ NO: 6 and capable of specific binding, indirectly or directly to a native human FcεRI receptor wherein said first polypeptide sequence comprises human IgG1 constant region, said second polypeptide consists of the CH2, CH3, and CH4 domains of human IgE heavy chain constant region through a polypeptide linker consists of 15 to 25 amino acid residues and said fusion molecule is SEQ ID NO: 7, a pharmaceutical composition comprising said fusion molecule and an article comprising said fusion molecule, classified in Class 424, subclass 192.1.
- VI. Claims 55-61 and 62-67, drawn to an isolated nucleic acid molecule encoding a fusion molecule, vector, host cell, a pharmaceutical composition and an article comprising said isolated nucleic molecule, classified in Class 536, subclass 23.4, Class 435, subclass 69.1, Class 435, subclass 252.3.
- VII. Claims 68-72, drawn to a method for the treatment of IgE-mediated hypersensitivity reaction in humans, classified in Class 424, subclass 192.1.

The inventions are distinct, each from the other because of the following reasons:

- A. Groups I-VI are distinct and unique products (fusion polypeptide and polynucleotide) which differ with respect to their physiochemical properties, structure, amino acid composition, and therefore they are patentably distinct.

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B. Groups (VII) and (I-VI) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)).

In the instant case, the fusion peptide can be used as an immunogen to produce antibodies as well as therapeutic methods claimed.

In the instant case, the polynucleotide can be used to produce the proteins of interest as well as therapeutic methods claimed. Therefore, they are patentably distinct.

4. This application contains claims directed to the following patentably distinct species of allergens identified by SEQ ID NOS: 8-173.

These species are distinct because the allergens from food to pollen allergens differ with respect to their structures, physiochemical properties, and their site of action.

5. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species of allergen identified by SEQ ID NO for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, and 55 are generic.

6. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

7. Because these inventions are distinct for the reasons given above and the searches are not co-extensive, restriction for examination purposes as indicated is proper.
8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 8:00 am to 5:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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11. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Phuong N. Huynh, Ph.D.
Patent Examiner
Technology Center 1600
June 28, 2001


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600